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NATIONAL SHELLFISH SANITATION PROGRAM MANUAL OF OPERATIONS. PART III. PUBLIC HEALTH SERVICE APPRAISAL OF STATE SHELLFISH SANITATION PROGRAMS

Public Health Service
Washington, D. C.

1965

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NATIONAL SHELLFISH SANITATION PROGRAM MANUAL OF OPERATIONS

Part III

PUBLIC HEALTH SERVICE APPRAISAL OF STATE SHELLFISH SANITATION PROGRAMS

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INFORMATION SERVICE
U S Department of Commerce
Springfield VA 22151

U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Public Health Service
Division of Environmental Engineering and Food Protection
Shellfish Sanitation Branch
Washington, D.C. 20201

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Introduction

Since 1925 the Public Health Service has cooperated with the several States and the shellfish industry in a program designed to insure that shellfish shipped in interstate commerce will be safe to eat. Under this National Shellfish Sanitation Program, each of the participating groups, i.e., the States, the Public Health Service, and the shellfish industry, has accepted certain specified responsibilities. These areas of responsibility are as follows:

1. **The States.**—Each shellfish-shipping State adopts adequate laws and regulations for sanitary control of the shellfish industry, makes sanitary and bacteriological surveys of growing areas, delineates and patrols restricted areas, inspects shellfish plants, and conducts such additional inspections, laboratory investigations, and control measures as may be necessary to insure that the shellfish reaching the consumer have been grown, harvested, and processed in a sanitary manner. The State annually issues numbered certificates to shellfish dealers who comply with the agreed-upon sanitary standards, and forwards copies of the interstate certificates to the Public Health Service.

2. **The Public Health Service.**—The Public Health Service makes an annual review of each State's control program, including the inspection of a representative number of shellfish-processing plants. On the basis of the information thus obtained, the Public Health Service either endorses or withholds endorsement of the respective State control programs. For the information of health authorities and others concerned, the Public Health Service publishes a semimonthly list of all valid interstate shellfish shipper certificates issued by the shellfish control authorities. In addition, the Public Health Service carries on a shellfish sanitation research program and assists the States in investigation of problems of unusual nature. However, for the purpose of the National Shellfish Sanitation Program, primary emphasis is placed upon the continuing appraisal of State programs to determine that a satisfactory level of sanitation is, in fact, maintained.

3. **The Industry.**—The shellfish industry cooperates by obtaining shellfish from safe sources, by providing plants which meet the agreed-upon sanitary standards, by maintaining sanitary plant conditions, by placing the proper certificate number on each package of shellfish, and by keeping and making available to the control authorities records which show the origin and disposition of all shellfish.

The need for objective procedures to guide the Public Health Service in reviewing each State program, and for specific criteria for PHS endorsement of State programs were discussed at the 1954 and 1956 Shellfish Sanitation Workshops. At the latter Workshop it was requested that the Public Health Service undertake the development of such procedures and criteria. This manual has been developed in accord with this recommendation. Advice and assistance in its development were sought from the control agencies in each of the participating States, interested Federal agencies, Canadian Federal departments, and the shellfish industry, as represented by their trade association, the Oyster Institute of North America. Our sincere appreciation is expressed to the many individuals in these agencies and organizations who have contributed time and technical advice to this project.

The provisions of this manual were reviewed and adopted for interim use by the participants at the 1961 Shellfish Sanitation Workshop held in Washington, D.C., on November 28–30, 1961. The manual was used on an interim basis until the 1964 Shellfish Sanitation Workshop held in Washington, D.C., on November 17–19, at which time its use was again discussed and it was thereupon adopted in its present form.

EUGENE T. JENSEN,
Chief, Shellfish Sanitation Branch, Division of Environmental Engineering and Food Protection, Public Health Service.

Definitions

National Shellfish Sanitation Program.—The National Shellfish Sanitation Program for the Certification of Interstate Shellfish Shippers as described in Public Health Service Publication No. 33, Part I, *Sanitation of Shellfish Growing Areas*, and Part II, *Sanitation of the Harvesting and Processing of Shellfish*.

Rating Officer.—The PHS employee assigned to appraise the effectiveness of the State Shellfish Sanitation Program.

State shellfish control agency.—The State agency or agencies having legal authority to classify shellfish-growing areas and/or to issue permits for the interstate shipment of shellfish in accord with the provisions of the National Shellfish Sanitation Program.

State shellfish patrol agency.—The State agency having responsibility for the patrol of shellfish-growing areas.

Representative number.—

Number of units: [1]	*Minimum number to be inspected* [2]
less than 25	All
25–54	25
55–59	26
60–64	27
65–71	28
72–78	29
79–86	30
87–94	31
95–105	32
106–116	33
117–130	34
131–147	35
148–167	36
168–191	37
192–222	38
223–262	39
263–316	40

[1] Interstate shippers, boats, trucks, oyster culture rafts, etc.

[2] Units to be chosen at random.

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Section A

EXERCISE OF PUBLIC HEALTH SERVICE RESPONSIBILITIES IN THE NATIONAL SHELLFISH SANITATION PROGRAM

1. Discussion.—The National Shellfish Sanitation Program for the Certification of Interstate Shellfish Shippers was established by a conference of Federal, State, and municipal authorities and representatives of the shellfish industry in February 1925 following a major outbreak of typhoid fever in the United States attributed to sewage-polluted oysters. The formation of the program and its basic concepts are described in "Report of Committee on Sanitary Control of the Shellfish Industry in the United States," Supplement No. 53, to the Public Health Reports. These stated concepts include:

1. Each producing State will be directly responsible for the effective regulation of all production and handling of shellfish within its confines, not merely for the protection of its own citizens but equally for safeguarding such of its product as goes to the other States.
2. The receiving States, being dependent upon the efficiency of the control exercised in the producing States, are entitled to full information concerning the scope and effectiveness of controls actually exercised in each producing State in order that judgment may be formed and action taken accordingly.

To implement the program, the 1925 conference agreed that the producing States would issue "Certificates," i.e., a permit to operate, to shellfish shippers meeting agreed-upon sanitary standards, and that the Public Health Service should serve as a clearinghouse for information on the effectiveness of the State control programs. This latter responsibility was met initially through issuance of a periodic "Progress Report on Shellfish Sanitation" describing the shellfish sanitation program in each State. This procedure was subsequently abandoned in favor of a "program endorsement" concept. Under this concept, the Public Health Service makes a continuing appraisal of each State's shellfish sanitation program to determine if the control measures are in substantial accord with the provisions of the current "Manual of Recommended Practice for Sanitary Control of the Shellfish Industry." The Public Health Service also publishes a list of all shellfish shippers certified by those States having "satisfactory" control programs.

The adoption of the "program endorsement" concept changed the role of the Public Health Service from fact-gathering to appraisal. To facilitate the use of the endorsement concept, a numerical appraisal procedure was developed in 1945. Because of the number of variables and lack of detailed instructions, the appraisal procedure tended to be rather subjective except for the inspection of shipper establishments where a more objective procedure was developed on the basis of experience in the milk and restaurant industries.

Experience demonstrated that the unqualified "program endorsement" concept was not entirely satisfactory because of the subjective qualities of the appraisal procedure and the nature of the Public Health Service responsibilities in the National Shellfish Sanitation Program. These shortcomings were discussed at the 1954, 1956, and 1958 Shellfish Sanitation Workshops. In accord with recommendations made at these meetings, the Public Health Service undertook the collaborative development of an objective appraisal procedure acceptable to the States and the shellfish industry, and the establishment of minimum criteria for Public Health Service endorsement of a State program.

2. **Procedure.**—The following procedure will be observed by the PHS in fulfillment of its obligation in the National Shellfish Sanitation Program:

a. Each State desiring to participate in the National Shellfish Sanitation Program will submit a formal request to the PHS Regional Health Director: *Provided*. That this requirement will apply only to States entering the program on an original basis or after a lapse in participation. This request, to be signed by the senior official of the State agency having primary responsibility for shellfish sanitation control, shall include a statement to the effect that an interagency agreement exists between the State agencies sharing program responsibilities and that the State recognizes its responsibilities and obligations in the National Shellfish Sanitation Program, and is willing to assist the PHS in making necessary reviews and inspections for State program appraisal. State participation in the National Shellfish Sanitation Program can thereafter be continuous; i.e., States will not have to file an annual notice with the PHS of their intent to participate in the program subsequent to the initial request. However, the regional offices may, at their discretion, request that States signify yearly their desire to participate in this program for the following fiscal year of the State. A State may withdraw from the National Shellfish Sanitation Program at any time upon written notification to the Regional office of the PHS.

b. PHS will complete a yearly appraisal of each State shellfish sanitation program, utilizing the procedures described in this manual. Field visits will be prearranged with States. PHS will initiate arrangements for such visits. PHS will submit trip reports to the States describing any corrective actions which should be taken by the States.

c. PHS will make periodic spot checks of States shellfish sanitation activities, particularly patrol and plant sanitation operations.

d. PHS will publish a yearly report on the status of the National Shellfish Sanitation Program. This report will describe progress made in both administrative and technical aspects of the program, will discuss problems which must be faced by the program, and will present a statistical review of the State activities. Neither comparative nor specific ratings for individual States will be shown in this yearly status report. The report will be made available to all persons interested in the National Shellfish Sanitation Program and, if feasible, will be published in a condensed form in a suitable technical journal.

e. A State program with a rating of less than 70 percent in any one of the eight identified program elements—general administrative procedures, laboratory, sanitary survey, relaying, depuration, patrol, harvesting, and shucking-packing—will not be eligible for endorsement by the Public Health Service 90 days after being formally notified of the rating unless the State demonstrates that suitable corrective action has been taken. Withdrawal of the State program endorsement will be initiated by the PHS Regional Office after discussion with the appropriate State officials, and will be subject to review through established PHS policy channels at Headquarters level. If the State desires participation in the National Shellfish Sanitation Program subsequent to PHS withdrawal of endorsement, the director of the State agency having primary responsibility for shellfish control must make application to the Regional Health Director for reappraisal of the State's program. In submitting this application, the State shall describe the measures taken to correct the noted deficiencies.

f. In an emergency situation, the PHS will take immediate steps to temporarily suspend endorsement of a State program when it is found that a condition exists in which interstate shipment of shellfish therefrom would be likely to cause disease. Such action will be initiated by the Regional Program Director through established communication channels after first advising the State of the proposed action.

g. PHS will publish a periodic list of shellfish shippers certified by the endorsed States.

h. PHS will keep the Food and Drug Administration informed of technical and administrative developments in the National Shellfish Sanitation Program in accord with the existing intradepartmental agreement (Appendix A).

i. PHS will keep the Fish and Wildlife Service fully informed of technical and administrative developments of the National Shellfish Sanitation Program in accord with the existing interdepartmental agreement (Appendix B).

Section B

APPRAISAL PROCEDURE

1. **Discussion.**—To provide satisfactory public-health protection to consumers of shellfish, a State shellfish sanitation program should include the following elements: legal authority; evaluation of sanitary conditions of growing areas; sanitary control of relaying and purification; prevention of harvesting from polluted areas; sanitary supervision of the harvesting and packing of shellfish; and laboratory facilities. The specific requirements for these elements are described in Parts I and II, *Manual of Operations for Sanitary Control of the Shellfish Industry*, PHS Publication No. 33. These requirements are revised periodically through joint action of the interested parties.

PHS endorsement of a State program is contingent upon the attainment of a satisfactory level in *each* of the several critical elements. In appraising these several program elements, the Public Health Service will be guided by the most current revision of PHS Publication No. 33, Parts I and II. The complete cooperation of the State is expected in making these appraisals; e.g., *it will be the responsibility of the State to produce evidence that all program elements are, in fact, satisfactory.* States will supply the rating officer with copies of all necessary reports, and with such details of sanitary surveys and inspections as it may require to complete the appraisal.

The primary purpose of the program appraisal is to evaluate the degree of compliance with the agreed-upon practice of the National Shellfish Sanitation Program. The appraisal will delineate specific areas of strength or weakness in the State's shellfish sanitation program, and may point out ways in which State programs may be improved; however, this should not be confused with the primary purpose of the appraisal.

Rating appraisals will be initiated annually by the Public Health Service unless advised that the State no longer wishes to participate in the National Shellfish Sanitation Program. The rating officer will make the necessary arrangements with the State officials well in advance of the date selected, and will ordinarily make all phases of the review in the company of State officials. The rating officer will also normally make a limited number of spot checks of patrol activities and plant sanitation levels each year. The amount of time required to complete the evaluation of a State program will ordinarily depend upon the size, importance, and complexity of the shellfish industry in the State.

The evaluation of State laboratory procedures will ordinarily be performed by a laboratory review officer with recognized competence in the area being evaluated; i.e., bacteriology or toxicology. Copies of laboratory evaluation will be included in the overall State program appraisal report.

Two copies of the State program appraisal, together with the regional recommendation for endorsement, will be forwarded to the PHS Headquarters office by June 30 of each year. The Regional office will also forward copies of the completed review to the Senior Administrative Officer of each State agency involved in shellfish sanitation activities. Any necessary conferences between the regional staffs and State staffs shall normally be completed prior to the forwarding of the final appraisal to the Headquarters office. The format of the report is described in section C. In the event a State disagrees with their appraisal, it is understood that they have the right of appeal to the PHS Headquarters office: *Provided*, Such appeals are made within 30 days of their receipt of the appraisal.

2. **Administrative Practices.**—The rating officer will complete Form I in evaluating the adequacy of the legal and administrative elements in the State's control program. Instructions for completing this form will be found on pages 7 and 8. Data for this review will ordinarily be obtained from analysis of State records; however, these data will be subject to confirmation through field observations. Some States have delegated the responsibility for cer-

tain administrative aspects of the program to county, district, or local governmental jurisdictions. In all such cases, the State will be considered as responsible for satisfactory operation. The States will also be expected to have adequate data readily available on which the rating officer can justify an opinion as to the adequacy of these decentralized operations.

FORM I.—*Appraisal of general administrative procedures*

State Period Rating officer

The number and letter subitems below refer to PHS Publication No. 33, Part I, Section A.	Weight	Weight applicable	Percent compliance	Score
1. Adequate legal basis for—				
a. Classification of actual or potential growing waters	10			
b. Patrol, apprehension and effective prosecution	10			
c. Supervision of relaying, depletion, wet storage and purification	5			
d. Regulating the handling of shellstock	3			
e. Preventing ceritfied shippers from handling shellfish from noncertified sources	3			
f. Establishing sanitary standards for all classes of certified shellfish shippers	2			
g. Emergency restriction on harvesting or shipping	5			
h. Preventing the sale, shipment or possession of nonidentified shellfish	2			
2. General administrative practices—				
a. Requirements applied to all actual or potential growing waters	10			
b. Requirements applied to all commercial harvesters	10			
c. Requirements applied to all persons (excluding harvesters) handling shellfish prior to the certified shipper	10			
d. Certificates issued only to establishments meeting basic construction requirements and revoked when sanitation rating falls below 80% or if item is repeatedly violated	10			
e. Adequate central records of sanitary surveys, patrol activities (including arrests and results of prosecution) and plant inspections	10			
f. Guidelines observed in the issuance of certificates	2			
g. Regional office notified of growing area reclassification	1			
h. Plant inspectors have necessary inspection equipment	2			
i. Interdepartmental memorandum of understanding complies with manual requirement	5			
Total				
	Final rating			

Are controls based on statutory or administrative law?

Give appropriate paragraph references to laws or regulations.

Have there been any changes in laws or regulations since last evaluation? If so, describe.

REMARKS: (Discuss any significant differences in State requirements for interstate and intrastate shippers.)

Instructions for Completion of Form I

Item 1: The subitems listed under this item relate to the legal authority for the State's program. Review of the legal aspects of the State shellfish laws and regulations shall be made with the Regional Attorneys. Full credit is to be given on each subitem if, in the Regional Attorney's opinion, it is the intent of the law or regulation regardless if the State is actually carrying them out in practice. Deductions should be made from item 1, Form 1, only if the State clearly does not have adequate legal authority to carry on a program, or if the laws and regulations are not enforceable because of their nature. Deductions should also be made under this item if the legal authority is lacking, even though field studies indicate a satisfactory program. Partial scores may be given for the individual items.

Appropriate deductions should be made in Forms III, IV, VI, or VII if field investigations indicate that the subitems listed under item 1, Form 1, are not being complied with.

Item 2: This item relates to the administrative practice *used* by the State.

(a) Partial credit will not be given.

(b) Partial credit will not be given.

(c) Partial credit will not be given.

(d) Partial credit will be given. (In the event that inspection discloses establishments which are not eligible for certification as described in Part 1, immediate arrangements will be made by the States for the correction of the observed defects or for State suspension or cancellation of the certificates. If the State does not notify the rating officer that such steps have been promptly taken, the rating officer will advise the State control agencies, the Food and Drug Administration district office, and the Public Health Service Headquarters of the defective establishments.)

(e) (1) Credit shall be based on the number of complete growing area files relative to the total number of growing areas. Growing areas may be identified by number, name, political or geographic boundaries.

(2) Monthly patrol reports are to be submitted to the PHS regional office. Credit will be based on the number of such reports received, and the adequacy of the information contained therein.

(3) Monthly summaries of plant inspection activities are to be maintained by the State in a central inspection report file. Credit given will be based on the proportion of plants inspected relative to the number which should have been inspected. Shucker-packers are to be inspected on a monthly basis during periods of operations. Other classes of shippers to be inspected according to a frequency acceptable to the State and the Regional office. This latter inspection frequency will be indicated in "Remarks."

(f) Credit will be given on the basis of compliance with the basic item. Each numbered subitem, i.e., content, changes, prior shipment, cancellations, and use of mailing lists will be given equal weight. Deductions will not be prorated on the basis of observed violations.

(g) Any violation will forfeit the entire item.

(h) Credit should be given on the basis of equipment provided all inspectors. Partial credit may be given on the basis of number of inspectors involved, and equipment deficiencies.

Item 3: *Intrastate Sale of Shellfish.*—If it is clear from a review of the State regulations or inspection of intrastate shippers that standards for intrastate shippers are lower than those for National Shellfish Sanitation Program shippers, this observance, together with a discussion of the problem and the total number of intrastate shippers, should be noted in "Remarks."

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3. **Laboratory Procedures.**—Attempts will ordinarily be made to have laboratory reviews made by PHS staff members who are particularly competent in the area being reviewed. However, the rating officer will be expected to discuss the laboratory procedures with appropriate state officials to ascertain that generally acceptable methods are used. The rating officer will originate the request for service of the laboratory review personnel.

The rating which is given for laboratory procedures will be based upon the number of laboratories involved and the degree to which these laboratories use currently accepted methods in making bacteriological, toxicological, chemical, and physical determinations. The rating officer should note that not all such determinations are made exclusively by laboratory personnel; e.g., salinity measurements may be made by the field staff using a hydrometer. Form II should be completed on the basis of information obtained by the rating officer in (1) discussion with State laboratory and staff personnel, and (2) on detailed information submitted to the rating officer by the laboratory review specialists.

The laboratory review officer will direct his appraisal of State laboratory facilities to the rating officer. The report should be such as to enable the rating officer to complete Form II. A supplementary narrative report which can be transmitted to the responsible State official will also be provided.

4. **Growing Area Survey and Classification.**—The rating officer will ordinarily emphasize the appraisal of the "Growing Area Survey and Classification" aspect of State programs because of the established relationship between shellfish-caused disease and pollution of growing or holding areas.

Appraisal of this element will usually include (1) an office analysis of all sanitary surveys and resurveys of all "Approved," "Conditionally Approved" and "Restricted" areas; (2) field visits to a representative number of the "Approved" and "Restricted" areas; and (3) field visits to all "Conditionally Approved" areas. The field visit will enable the rating officer to partially verify the sanitary survey data in the State files. The rating officer will place emphasis on his appraisal of variable sources of pollution, i.e., sewage systems and boats, and on the degree to which such sources of pollution were considered in area classification.

FORM II.—*Evaluation of laboratory procedures*

State _____ Period _____

Rating officer _____

Location of laboratory	Weight	Items applicable	Percent compliance	Score
Part A: Bacteriological				
Subtotal	40			
Part B: Toxic Shellfish Poison				
Subtotal	40			
Part C: Chemical and Physical				
Subtotal	20			
Total				
Weighted final rating				

Remarks: _____

Instructions for Completion of Form II

1. *Location.*—The name or location of each laboratory should be indicated. In Part C, the type of examination made should be indicated by a suitable code to be explained in "Remarks."

2. *Weight.*—The relative importance of the laboratory in making the particular type of examination should be indicated. Note that the subtotals equal 40 for bacteriological examination, 40 for toxic shellfish poison, and 20 for chemical and physical determinations.

3. Appropriate entries should be made in the column to indicate any items which are not applicable; e.g., many States have no reason to assay for paralytic shellfish poison.

4. Percent compliance should be based on the analysis of reliability of techniques used by the particular laboratory.

5. *Score.*—Score is the product of the weight and percent compliance.

6. The final weighted result is computed by dividing the total "Score" by total "Items applicable." The results should be converted to a percentage by multiplying by 100.

7. The name of the laboratory review officer, or officers, should be entered under "Remarks."

The rating officer will review each survey jointly with his counterpart in the State shellfish control agency. If in the course of review, defects were noted which might result in the interstate spread of disease, the rating officer shall immediately notify the senior officer of the State shellfish control agency and the Public Health Service Headquarters office of these conditions. The rating officer and the State officials shall take whatever steps may be necessary and feasible to prevent the interstate shipment of such contaminated or dangerous shellfish.

Form III, Evaluation of Sanitary Surveys and Resurveys, will be initially completed by the rating officer on the basis of information obtained through his review of the State-maintained growing area files. These data will then be corroborated by field inspection. The rating officer, in the company of a State agency representative, will visit a representative number of approved and restricted growing areas to determine if the information in the growing area files portrays accurately those conditions which influence the sanitary quality of the areas. Where possible, program appraisals should be so scheduled that all "Approved" areas will be reviewed at least once during each 4-year period.

The rating officer will consider the bioassay surveillance program as a component of the sanitary survey in those areas in which toxic shellfish poison may reasonably be expected to occur. An approximate weight of 40 percent should be applied to those areas in which this item is applicable. For example, a growing area sanitary survey might be rated as 87 percent, but it might be determined by inspection that the bioassay surveillance program was defective. In this case, a 40-percent deduction should be made with a resulting value of 47 for the areas involved.

Growing areas having a sanitary survey rating of less than 70 percent should not ordinarily be approved for further harvesting of shellfish for direct marketing.

5. **Relaying, Depletion, and Depuration.**—Adequate public-health control of relaying, depletion, and controlled depuration is essential because these practices permit the eventual marketing of shellfish which were initially dangerously polluted. The degree to which these procedures are utilized varies greatly in the several States. Also, the relative importance of effective control varies with the initial quality of the shellfish.

To appraise the effectiveness of relaying, depletion, and controlled depuration operations, the rating officer should review the office records of the State agency and, to the extent possible, should make field checks to verify the accuracy of these records. The rating officer should attempt to observe at least one depletion operation and should review all records of other depletion operations which have been carried on. In completing Form IV, the rating officer should observe the following general guides: (a) the transportation of shellfish between Approved areas is not relaying; (b) the transplanting of seed shellfish, i.e., submarket sized shellfish, is not relaying; and (c) shellfish relaying during periods when shellfish may not be legally harvested for conservation or other reasons is not relaying, provided such operations are concluded at least two weeks in advance of the legal harvesting season. In completing Form IV, the rating officer should allow credit in proportion to the percentage of the relayed shellfish which are handled in accord with the provisions of PHS Pub. No. 33, Part I.

6. **Control of Harvesting From Closed Areas.**—In many States the prevention of commercial shellfish harvesting from polluted or toxic areas has importance equal to or greater than that of any other element. However, adequate appraisal of this program element is difficult because of the widely varying technical and administrative situations which are encountered. For these same reasons, the National Shellfish Sanitation Program has not developed patrol requirements with the same specificity as those applied to sanitary survey or plant inspection elements.

The rating officer will concentrate on identifying and evaluating the apparent strengths or weaknesses of the system. The rating officer will not be expected to prove that a State patrol system is inadequate, but only to show that the system is such that violators might go unapprehended or that the prosecution is such that there is insufficient deterrent to violators.

FORM III.—*Evaluation of sanitary surveys and resurveys*

State		Period		Rating officer			
Area		Surveys		Credit for effective date of survey	Quality of survey	Deduction for faulty toxicity surveillance	Score
Designation	State classification	Date of last survey or resurvey	Date of last appraisal				
1	2	3	4	5	6	7	8
Final rating							

Instructions for Completion of Form III

Area Designation and Classification.—Areas may be designated by geographic name, number, or political boundary. The rating officer may, and with concurrence of the State, consolidate adjacent areas into more convenient units to facilitate ratings. Such consolidated areas should be described in terms of latitude and longitude coordinates or by reference to established locations on Coast and Geodetic Survey charts. Information positively locating the area will be included as a supplement to Form III so that future program ratings will be based upon the same general areas. Classifications should be in accord with the definitions of Section C-2, Part I: 1965 Manual of Operations for the Sanitary Control of the Shellfish Industry. The following abbreviation should be used: *Conditionally Approved* =CA; *Approved* =A; *Restricted*=R; and *Prohibited*=P.

If the State does not use this classification system, a footnote explaining the State system shall be appended to Form III. Each designated growing area, regardless of its size or relative shellfish production, is to be considered of equal weight and importance in the computation of Form III.

Date of Last Completed Survey.—This date should be obtained from the State area file. If the date is indefinite or if an area file is not available, a note to this effect should be entered in column 2, and be treated as zero in computations. Where a new area is being approved, the date of the initial survey will be entered in column 3.

Date of Last Resurvey.—This information should be entered in the same manner as in column 3.

Credit for Effective Date of Survey.—A percentage

value will be entered in column 5 according to the following schedule:

Sanitary survey or resurvey within 10 years and reappraisal as follows:

	Credit (percent)
a. Reappraisal within 2 years	100
b. Reappraisal within 3 years	85
c. Reappraisal within 4 years	10
d. Reappraisal over 4 years	0

Sanitary survey over 10 years and no resurvey: zero percent credit.

Quality of Survey.—The rating officer will review survey and resurvey area files and will assign percentage values to each area on the basis of the following criteria:

	Percent
Sanitary evaluations of sources of pollution including sewerage systems	40
Evaluation of hydrographic factors responsible for spread of pollution	10
Bacteriological, chemical (including pesticides), and radiological survey of shellfish growing areas as indicated	25
Analysis of the interrelationships of the foregoing factors and resulting area classification	25

Partial credits may be allowed in using the above criteria.

The weight which will be attached to any particular item will depend upon prevailing conditions; e.g., in considering a growing area remote from any source of pollution, the rating officer will recognize that the sanitary quality of the area can be established without extensive field or laboratory study.

The rating officer will make suitable adjustments in the rating assigned on the basis of file review if field conditions are found which indicate that the survey is incorrect, or if significantly changed conditions are not reflected in the area classification.

A brief narrative statement shall be prepared describing each deduction for each growing area.

Deduction for Faulty Shellfish Toxicity Surveillance.—The surveillance program, incorporating an assay procedure, will be considered as a component of the sanitary survey in those areas in which shellfish toxicity may reasonably be expected to occur. If the inspection shows that the surveillance program is defective, then the rating officer should apply a 40-percent deduction to the area sanitary survey rating (product of col. 5 and col. 6).

Score.—Score is the value which results when the product of column 5 and 6 is divided by 100, minus deduction for faulty area surveillance program for naturally occurring shellfish toxins.

A brief, narrative statement should be prepared describing each deduction.

Final Rating.—Final rating is the arthimetical average of the scores of the designated growing areas expressed as a percentage.

FORM IV.—*Control of relaying and depletion operations*

1. Percentage of total State shellfish production which is relayed ..... percent.

	Weight	Applicable	Percent	Score
2. Effectiveness of relaying controls:[1]				
a. Written approval for each relaying and depletion operation	10			
b. Under immediate supervision of State including patrol of relaying area and adequate tests.				
(1) Supervision of relaying operations	20			
(2) Patrol of relaying areas	10			
(3) Records of water quality	5			
c. Permission to relay shellfish only to responsible person	5			
d. Shellfish held for adequate period of time				
e. Relayed shellfish harvested only by wirtten permission	10			
f. Relaying areas designated and identified	5			
3. Effectiveness of depletion controls:[2]				
a. Under immediate supervision of State including patrol of relaying area	20			
b. Effectiveness of depletion operation	10			
c. Evaluation of need for new depletion operations	5			
			Final rating	

[1] Items refer to Section D, Part I, PHS Pub. No. 33.
[2] Items refer to Section E, Part I, PHS Pub. No. 33.

Instructions for Completion of Form IV

Item 1. Percentage of Shellfish Relayed.—State records should be reviewed and, where possible, verified by discussions with shellfish shippers or with other State agencies which share responsibility for supervision of the operation.

Item 2. Effectiveness of Relaying Controls (a, b, and c).—The rating officer will not be expected to demonstrate that the control system is unreliable, but only that the facilities and organization which the State has provided are such that violations might reasonably be expected to occur. This attitude must be adopted since it is obviously impossible for the rating officer to personally observe each relaying operation. Consequently, discovery of a violation by the rating officer would be only through accident or coincidence.

The rating officer may make partial deductions for an item if it is clear that the deficiency is applicable to only a portion of the State's relaying program.

(d) The effectiveness of relaying depends upon the shellfish being left in the approved area for a period of time sufficient for purification to take place. If any violation is found of this item, the credit for the entire relaying item will be forfeited. The item will be assumed to be violated if records indicate that shellfish have been held in the area for less than 14 days at a suitable temperature unless the State has satisfactory evidence that a lesser period of time is adequate to accomplish purification.

(e) State records should be consulted and verified by discussions with shellfish dealers and with other State agencies that share responsibility for this operation.

(f) Credit will be in proportion to the number of areas that are properly identified.

Item 3. Effectiveness of Depletion Controls.

(a) Same as Item 2 (a, b, and c), supra.

(b) The effectiveness of depletion operations depends upon all market shellfish and as many of the smaller size shellfish as can be gathered by reasonable methods being removed from the area.

(c) Evaluation for need of new depletion operations to be carried out at intervals to prevent the development of market-sized shellfish is a necessary requirement of the depletion operation.

Form V.—*Depuration*

State _____ Period _____

Rating Officer _____

1. Number of depuration plants _____

2. Percentage of total State shellfish production subjected to controlled depuration _____

3. Effectiveness of depuration

Item [1]	Weight	Applicable	Percent	Score
(a) Demonstrated effectiveness	--------			
(b) Operating procedure	20			
(c) Bacteriological quality of water	40			
(d) Chemical quality of water				
(e) Shellfish washed before purification	3			
(f) Shellfish culled before purification	10			
(g) State supervision	5			
(h) Laboratory control	10			
(i) Trained operator	5			
(j) Limited access	2			
(k) Worker health	5			
(l) Controlled harvesting	([1])			
Total				
Weighted total				
Deduct for improper harvesting				

[1] Letter refers to Part 1, Section D, Item 2.

Instructions for Completion of Form V

3. *Effectiveness of depuration*

(a) A depuration plant operating procedure shall be developed for each depuration plant. The procedure should demonstrate that the method used will result in effective purification. Any violation of this requirement will result in zero credit regardless of the scores obtained on other aspects of the purification operation. However, the rating officer should complete the entire evaluation of the item even though the portion dealing with them (a) is violated.

(b) Credit for this item will depend upon (1) receipt of the State's operating procedures; and (2) their completeness.

(c through f) Partial credit may be allowed for these items.

(g) Same as item (a), supra.

(h) Credit for this item will be based on the degree to which the necessary tests are made. If nonstandard procedures are used, deductions should be made on Form II, Laboratory Procedures, Part B.

(j and k) Partial credits may be allowed for these items.

(l) The rating officer shall assure himself that the State has an administrative system which insures that shellfish harvested from "Restricted" areas will, in fact, be submitted to purification before marketing. However, the rating officer will not be expected to demonstrate that lapses have actually occurred. If there is any deficiency in this item, the entire item for the purification plant will be forfeited.

A necessary step preliminary to the evaluation of a State patrol program is a joint State-PHS evaluation of the patrol problems, and a determination of the type of patrol organization and extent of patrol coverage that is required to achieve the desired results. The results of such conferences between representatives of the State and the PHS regional staff shall be documented and kept on file in the Regional Office. This patrol document shall review and clarify the following elements: (1) method of identification of closed areas; (2) type of patrol problem; (3) listing of areas to be patrolled; (4) frequency and nature of patrol; (5) type and frequency of reporting; and (6) public-educational measures. The patrol document shall be reviewed annually and be revised when necessary.

The rating officer should recognize that not all patrol activities may be carried out at the State level. However, the State delegation of responsibility for elements of the control program to local organizations will not absolve the State from the obligation of providing information on the effectiveness and completeness of these operations. The rating officer should, therefore, consider the local patrol operations as an intergral part of the State program.

7. **Evaluation of Harvesting Practices.**—Where possible, the rating officer should inspect a representative number of shell stock harvesting boats and prepare a numerical evaluation comparable to the sanitation rating for shucking plants. However, in some instances, this expenditure of staff time cannot be warranted because of the relative public-health significance of the item. In lieu of such a direct inspection, the rating officer will then (1) evaluate the State's system for obtaining approved sanitary measures, and (2) inspect only a small number of harvesting boats and/or transport conveyances. This information will be entered in Form VII.

8. **Evaluation of Shucking-Packing Practices.**—Representative numbers of packers, and repackers, will be inspected by the rating officer. Inspections should be recorded and ratings calculated as indicated in Appendix B, Part I, 1965 Manual of Operations for the Sanitary Control of the Shellfish Industry. Summary ratings for the several classes of shippers should be computed on PHS–770 and SS–3 forms. Copies of the individual inspection reports will not ordinarily be included in the rating officer's report.

In making these inspections the rating officer may discuss results with the State's counterpart official and may leave copies of the inspection report with the State official. If requested to do so by the State representative, the rating officer will also review the results of each inspection report with the plant management.

The ratings obtained through the inspection of these several classes of establishments will be combined into a final appraisal rating for shucking-packing practices as shown on Form VIII.

FORM VI.—*Evaluation of growing area control measures*

Part A

Area description	Adequacy of marking (percent)	Adequacy of patrol (percent)	Score
Final rating			

Part B

Patrol Equipment Review

Part C

Enforcement Proceedings

Instructions for Completion of Form VI

Part A

Area Description: As the first step in the calculation of the numerical ratings for the patrol activities, the rating officer should prepare a list of those areas which are not approved for commercial harvesting. This information should be entered in column 1. Each area should be so described that it can be readily identified in subsequent ratings.

Area Marking: The rating officer should visit a representative number of these areas to determine if the applicable requirements for boundary markers or area posters have been met. The degree of compliance will be determined for each area visited. This information will be recorded in column 2. In addition, the rating officer should visit "Prohibited" areas to attempt to determine any violation of the closure orders. In some instances, the rating officer should revisit areas to determine if the required markers and posters are still present. Any information obtained in such re-evaluations should be reflected by suitable corrections in Form VI.

Area Patrol: In appraising the patrol activities, the rating officer should compare State records of patrol activities with the previously-agreed upon levels of activity. The extent to which these two values agree should be entered in column 3 as a percentage. In the absence of complete records, the rating officer will ordinarily be unable to complete a review of this element of the State program. In such instances, no credit will be given for these elements for the State operation.

Score: The value entered for "Area Marking" and "Patrol Effectiveness" should be combined according to the following weights: Marking, 20 percent; Patrol,

80 percent. The resulting value should be entered in column 4, "Score (percent)."

Part B

The rating officer will prepare a narrative report on the appraisal of the equipment indicated in the policy document as necessary to carry on an effective growing area control program.

Part C

The rating officer will prepare a narrative report giving the number of apprehensions, the disposition of the cases, and an analysis of the factors which influenced the disposition of the cases. If the State agencies' experience in the courts suggests that State laws cannot be enforced effectively, an appropriate deduction should be made under item 1, page 7.

FORM VII.—*Evaluation of harvesting practices*

A. Number of State licensed harvesters _____
B. Estimated number of harvesting boats in State _____
C. Number of harvesting boats inspected _____
D. Estimated number of trucks used for shell stock transportation _____
E. Number of trucks inspected _____

Item	Weight	Item applicable	Percent compliance	Score
Construction and cleanliness of boats	40			
Construction and cleanliness of trucks	30			
Washing shell stock	10			
Waste disposal from boats	20			

Remarks _____

INSTRUCTIONS

A. Transfer information to columns 1, 2, and 3 from Inspection Reports (PHS-769-3)

B. Multiply each "*Final Plant Score*" by adjacent "*Number of Employees*" to obtain "*Weight.*"

C. Add column 3 and enter "*Total*" on final sheet of computation.

D. Add column 4 and enter "Total" on final sheet of computation. Divide "*Total Weight*" by "*Total Number of Employees*" to obtain "*Final Rating.*"

State	Number of shell-stock shippers	Number inspected	Date
Certificate number (1)	Final plant score (2)	Number of employees (3)	Weight (4)
	Total		
		Final rating	

Remarks

PHS-770
REV. 1-58

SHELLFISH SHUCKING-PACKING PLANTS INSPECTION SUMMARY

Page ______ of ______ pages

INSTRUCTIONS

A. Complete all blocks above column headings on each summary sheet.

B. Transfer information to columns 1, 2, 3, and 5 from inspection reports. Record number of shuckers to nearest 5. If less than 5 shuckers record as 1.

C. Subtract "DEDUCTIONS" from "INITIAL PLANT SCORE" to obtain "FINAL PLANT SCORE."

D. Multiply each "FINAL PLANT SCORE" by adjacent "NUMBER OF SHUCKERS" to obtain "WEIGHT."

E. Add column 5 and enter "total" on final sheet of computation.

F. Add column 6 and enter "total" on final sheet of computation. Divide "TOTAL WEIGHT" by "TOTAL NUMBER OF SHUCKERS" to obtain "FINAL RATING."

STATE	NUMBER OF SHUCKER-PACKERS	NUMBER INSPECTED	DATE

CERTIFICATE NUMBER 1.	INITIAL PLANT SCORE 2.	DEDUCTIONS 3.	FINAL PLANT SCORE 4.	NUMBER OF SHUCKERS 5.	WEIGHT 6.
REMARKS:			TOTALS		
				FINAL RATING	

Use additional copies of this Form for continuation sheets, if necessary.

FORM VIII.—*Evaluation of shucking-packing practices*

Type of shipper	Summary rating (percent)	Number of shippers	Weight	Score (percent)
Reshippers				
Shell-stock				
Shucker-packers				
Repackers				
Total				
		Final rating		

Remarks _____

Instructions for Completing of Form VIII

Summary Rating.—The summary ratings for each of the several classes of shippers (Forms PHS-770, SS-3, etc.) should be entered in this column.

Number of Shippers.—The number of each class of shipper should be brought forward from the summary rating forms.

Weight.—Values for this column should be determined by dividing each type of shipper by the total number of shippers.

Score.—Multiply column 2 "Summary rating" by column 4 "Weight" to obtain this value.

FORM IX.—*Summary appraisal of State Shellfish Sanitation Program*

Individual program elements	Rating (percent)
1. General Administration Procedures	
2. Laboratory procedures	
3. Sanitary survey	
4. Relaying and depletion	
5. Controlled purification	
6. Patrol	
7. Harvesting	
8. Shucking-packing	

Remarks _____

Section C

PREPARATION OF RATING OFFICER'S REPORT

The rating officer will prepare a report on each State shellfish sanitation program according to the following outline:

A. Introduction.—The introduction should indicate that the appraisal has been made in accord with Part III: "Public Health Service Appraisal of State Shellfish Sanitation Programs—Manual of Operations—National Shellfish Sanitation Program." The names and titles of all individuals participating in the appraisal should be given.

B. Summary of State Shellfish Sanitation Programs.

1. Form IX. Summary of Appraisal.
2. Narrative report. The narrative report should be concise and should include:
   (a) A statement as to the general status of the State's shellfish sanitation program.
   (b) A brief discussion of needs for specific program emphasis.
   (c) An appraisal of the adequacy of funds, personnel, and facilities available to the State agencies for carrying out all phases of the program.

C. Detailed Appraisal of Individual Elements of State Shellfish Sanitation Program.[1]

1. Form I—Appraisal of Legal and Administrative Procedures
2. Form II—Evaluation of Laboratory Procedures
3. Form III—Evaluation of Sanitary Surveys and Resurveys
4. Form IV—Control of Relaying Operations
5. Form V—Controlled Purification
6. Form VI—Evaluation of Growing Area Control Measures
7. Form VII—Evaluation of Harvesting Practices
8. PHS-770—Shellfish Shucking-Packing Plants Inspection Summary
   SS-3—Summary of Shell Stock Shipper Inspections
9. Form VIII—Evaluation of Shucking-Packing Practices
10. Form IX—Summary Appraisal of State Shellfish Sanitation Program
11. Form X—Combined Summary Rating (Appendix C).
12. Supplementary Narrative Report as needed to clarify information on the foregoing Forms and as called for by the appraisal procedure.

D. Appendix.—Additional information necessary to clarify the State appraisal. Photographs may be used.

[1] Any forms not applicable to the program being appraised may be omitted from the completed appraisal report.

Section D

SUPPLEMENTAL PROGRAM STATISTICS

The rating officer should assemble and forward the following information to the PHS Headquarters office by June 30 of each year for use in program planning. This material will not be included in the program appraisal forwarded by the regional office to the State agencies.

1. Estimated shellfish production together with any evident trends; i.e., an indicated decline or advance.

2. A brief description of the State organizations responsible for administration of the shellfish sanitation program including, where possible, the names of individuals.

3. An estimate of the total State expenditures for shellfish sanitation activities. This should include an estimate of expenditures for patrol activities.

4. A statement as to the amount of time required to complete the rating survey.

5. Information on any other elements of the shellfish industry which might be helpful in program planning.

6. An estimate of the proportion of shellfish production not subject to National Shellfish Sanitation Program requirements.

7. A statement of the problems associated with the sale of shellfish from foreign countries not having sanitation agreements with the United States.

8. A statement describing State control over the use of shellfish in products not covered directly by the certification program; e.g., breaded oysters or clams.

9. An estimate of yearly shellfish production from each of the identified growing areas.

Appendix A

Cooperative Agreement Between the U.S. Public Health Service and the Food and Drug Administration Relative to Sanitary Control of the Shellfish Industry, July 20, 1933

The agreement between the U.S. Public Health Service and the Bureau of Chemistry (now the Food and Drug Administration) is hereby reaffirmed. This agreement published in 1925, reads as follows:

In accordance with a cooperative agreement between the Public Health Service and the Bureau of Chemistry (Food and Drug Administration) the Public Health Service will furnish the Bureau of Chemistry (Food and Drug Administration) information regarding insanitary shucking houses and shellfish growing areas in order that interstate shipments may be dealt with as heretofore under the Federal Pure Food and Drugs Act.

The original agreement is supplemented as follows:

1. U.S. Public Health Service will request shellfish producing States to report all cancellations and withdrawals of shippers certificates of refusals to issue State certificates, and specify in the reports the reasons for such action. On receipt of this information the U.S. Public Health Service will in turn transmit the report to the Food and Drug Administration.
2. The U.S. Public Health Service will inform the Food and Drug Administration whenever the approval of State certifications is withdrawn or withheld.
3. The U.S. Public Health Service will report conditions in shellfish producing areas or in shucking plants which indicate probability that shellfish are being marketed in violation of the Federal Food and Drugs Act.
4. The Food and Drug Administration will inspect the sanitary conditions of all shellfish plants not certified, which may do an interstate business. Reports made of such investigations by the Food and Drug Administration will be furnished to the U.S. Public Health Service, with copies to the State shellfish control agency.
5. The Inspectors and agents of the Food and Drug Administration will keep in close touch with State shellfish control agencies and with representatives of the U.S. Public Health Service in matters pertaining to enforcement of the Federal Pure Food and Drug Act.

Appendix B

Memorandum of Understanding Between the Department of the Interior (Fish and Wildlife Service) and the Department of Health, Education, and Welfare (Public Health Service) Relative to the Certification of Interstate Shellfish Shippers

Whereas the Department of the Interior is charged by the Fish and Wildlife Act of 1956 with the responsibility for all matters primarily relating to fisheries; and

Whereas the Public Health Service of the Department of Health, Education, and Welfare is charged with preventing the transmission or interstate spread of communicable disease, and in fulfillment of this obligation has cooperated with the States, shellfish industry, Food and Drug Administration, and Fish and Wildlife Service of the Department of the Interior in a sanitary control program for the certification of interstate shippers of oysters, clams and mussels;

Now therefore in the interests of public health, efficiency, and economy; to insure that consumer confidence will be maintained in commerically produced and distributed shellfish as food; and for the purpose of defining their respective functions the Fish and Woldlife Service and Public Health Service do hereby mutually agree as follows:

The Fish and Wildlife Service, acting in a liaison and advisory capacity, and the Public Health Service, acting in a research and administrative capacity, will cooperate in maintaining a high level of sanitation in the oyster, clam and mussel industries so that shellfish will not contribute to the interstate spread of disease.

The Public Health Service will continue to cooperate with the States, shellfish industry, Federal agencies and the Canadian Government in the certification of interstate shellfish shippers. This may be accomplished through shellfish sanitation research, development of technical guides, periodic evaluation of State shellfish sanitation programs, endorsement of acceptable State programs, maintenance of liaison with the Canadian Federal agencies responsible for shellfish sanitation, and distribution of a list of State-certified interstate shellfish shippers. The Public Health Service will consult with the Fish and Wildlife Service during all phases of the development of technical guides and in the planning and direction of shellfish sanitation research projects. In the event of an interstate outbreak of disease attributed to a fishery product other than shellfish the Public Health Service will, whenever practicable, consult with the Fish and Wildlife Service prior to the institution of control measures.

The Fish and Wildlife Service, in its advisory capacity and through its qualified liaison representatives, will make available to the Public Health Service any available scientific information pertinent to the development of technical aides or to research projects undertaken by the Public Health Service as a necesary adjunct to the shellfish certification program. The Fish and Wildlife Service will disseminate, through industry contacts, information concerning the intent and the need for the shellfish certification program.

The Public Health Service will continue to request appropriations and to expend funds to support the shellfish sanitation activities described above.

(S) HATFIELD CHILSON,
Acting Secretary of the Interior.

May 22, 1958.

(S) M. B. FOLSOM,
Secretary of Health, Education, and Welfare.

July 24, 1958.

APPENDIX C

FORM X.—*Combined summary rating*

Program element	Weight	Item applicable	Percent compliance	Score
1. General administration procedures	10			
2. Laboratory procedures	5			
3. Sanitary survey	30			
4. Depuration	5			
5. Purification	10			
6. Patrol	30			
7. Harvesting	5			
8. Shucking-packing	5			
		Weighted total		

Instructions

The final rating obtained by this artificial combination of values is of limited utility; however, suc ratings based on a uniform procedure will measure year to year change, and may be used for comparative purposes.

Percent Compliance: Percent compliance values should be entered from Form IX "Summary Appraisal of State Shellfish Sanitation Program."

Score: Each "Item Applicable" and "Percent Compliance" value should be multiplied, with the products being recorded under "Score."

Weighted Total: "Weighted Total" should be readjusted in proportion to the total obtained under "Item Applicable."

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